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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/002,710	01/05/1998	MICHEL SCHNEIDER	1201-59	8110

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	**PAPER NUMBER**
1618	
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05/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/002,710	SCHNEIDER ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-115* is/are pending in the application.

4a) Of the above claim(s) *66-81* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *50-65 and 82-115* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESTRICTION INTO GROUPS

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 50, 51 (in part), and 52-57 drawn to contrast agents comprising a fluorinated gas and one or more phospholipids as set forth in independent claims 50-57, classified in class 424, subclass 1.89+.

Group II. Claim 51 (in part) drawn to a contrast agent comprising a halogenated hydrocarbon (other than fluorinated hydrocarbons) as set forth in independent claim 51, classified in class 424, subclass 1.85+.

Group III. Claims 58, 59 (in part), and 60-65 drawn to contrast agents comprising a fluorinated gas in combination with a polymer member as set forth in independent claims 58-65, classified in class 424, subclass 1.89+.

Group IV. Claim 59 (in part) drawn to a contrast agent comprising a halogenated hydrocarbon (other than fluorinated hydrocarbons) as set forth in independent claim 59, classified in class 424, subclass 1.85+.

Group V. Claims 82, 83 (in part), and 84-89 drawn to a method of making a contrast agent for ultrasonic echography having the steps as set forth in independent claims 82-89 wherein the components used in the method comprise a fluorinated gas in combination with one or more phospholipid, classified in class 424, subclass 1.89+.

Group VI. Claim 83 (in part) drawn to a method of making a contrast agent for ultrasonic echography having the steps as set forth in independent claims 82-89 wherein the components used in the method comprise a halogenated hydrocarbon

(other than a fluorinated hydrocarbon) in combination with one or more phospholipid, classified in class 424, subclass 1.85+.

Group VII. Claims 90, 91 (in part), and 92-97 drawn to a method of making a contrast agent for ultrasonic echography wherein the components necessary for the method comprise a fluorinated gas in combination with a polymer membrane as set forth in independent claims 90-97, classified in class 424, subclass 1.89+.

Group VIII. Claim 91 (in part) drawn to a method of making a contrast agent for ultrasonic echography wherein the components necessary for the method comprise a halogenated gas (other than a fluorinated gas) in combination with a polymer membrane as set forth in independent claim 91, classified in class 424, subclass 1.85+.

Group IX. Claims 98-105 drawn to a method of ultrasound imaging of the left ventricle wherein a suspension consisting of hydrogenated soya lecithin, dicetylphosphate, lactose, and a fluorinated gas as set forth in independent claims 98, 100, 102, and 104, classified in class 424, subclass 9.3+.

Group X. Claims 106-113 drawn to a method of ultrasound imaging of the left ventricle wherein a suspension comprising dipalmitoylphosphatidyl glycerol, a copolymer polyoxyethylene-polyoxypropylene, glycerol, and a fluorinated gas as set forth in independent claims 106, 108, 110, and 112, classified in class 424, subclass 9.3+.

Group XI. Claims 114 and 115 drawn to a method of ultrasound imaging of the left ventricle wherein a suspension comprising human serum albumin and a

fluorinated gas as set forth in independent claims 114 and 115, classified in class 424, subclass 9.3+.

Note: Claims appearing in more than one group will only be examined to the extent that they read on the elected invention.

2. The inventions are distinct, each from the other because of the following reasons.

Groups (V-VIII) and (I-IV) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)) (see reasoning below).

Groups (I-IV) and (IX-XI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h) (see reasoning below).

Groups I-XI are distinct from one another because each group requires a different product, method steps, and method of making the product in order to reach a desired goal. Also, while the methods of using the products for imaging are disclosed, the components involved in the various processes differ. For example, in the method of imaging of claim 108, a suspension consisting of dipalmitoylphosphatidyl glycerol, a

copolymer of polyoxyethylene-polyoxypropylene, glycerol and CF4 are utilized. However, in a method of imaging according to claim 115, human serum albumin in combination with a gas selected from the group consisting of CF4, C4F8, or C4F10 is utilized. Thus, one method (i.e., the method of claim 108) using the components specific to that method would neither be anticipated nor rendered obvious by the components of claim 115. Likewise, the product of claim 54 which requires one or more phospholipids and C4F8, for example, would be different from the product of claim 61 requiring a polymer membrane and SF6. Hence, the processes may involve materially different material.

3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

ELECTION OF SPECIES

4. Claims 50-65 and 82-115 are generic to the following disclosed patentably distinct species. The species may be fluorinated species (i.e., CF4, SF6, C4F10, or C4F8) comprising one or more phospholipids, halogenated hydrocarbons comprising one or more phospholipids, fluorinated gases in combination with a polymer membrane, halogenated hydrocarbons in combination with a polymer membrane. The species are independent or distinct because not only are they structurally different, but also one

combination would neither anticipate nor render obvious another combination. For example, a suspension containing CF4 and a phospholipids would neither anticipate nor render obvious a suspension containing a non-fluorinated hydrocarbon and a polymer membrane. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Note: Applicant is respectfully requested to elect a species from within the elected group above. The species should set forth, if appropriate for the elected group, specific halogenated/fluorinated gas, the specific phospholipid(s), and/or polymer membrane. It addition, Applicant is respectfully requested to list the claims directed to the elected species.

5. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Due to the complexity of the restriction requirement, a telephone call was not made to request an oral election to the above restriction requirement.

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

8. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

9. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

REJOINDER PARAGRAPH

11. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

COMMENTS/NOTES

12. Since claims 66-81 were lost in the interference, these claims were not considered in the restriction requirement above. Applicant is respectfully requested to cancel claims 66-81 which were lost in the interference.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D. L. Jones
Primary Examiner
Art Unit 1618

May 10, 2007